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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/528,250 | 06/21/2005 | Malcolm Carter | NV2-023US | 2767 |
| 959 7590 04/29/2008 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127 | | | | |
| EXAMINER | | | | |
| KIFLE, BRUCK | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1624 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,250

Applicant(s)

CARTER ET AL.

Examiner

Bruck Kifle

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 31-41 and 43-52 is/are pending in the application.
4a) Of the above claim(s) 1-26, 31-34 and 43-49 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 35-41 and 50-52 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Applicant's amendments and remarks filed 01/07/08 have been received and reviewed. Claims 1-26, 31-41 and 43-52 are now pending in this application.

Claims 1-26, 31-34 and 43-49 remain withdrawn drawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on 08/16/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 35-41 and 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the terms “heteroaryl,” “heterocyclyl” and “carbocyclyl,” the definitions provided in the specification is sufficient. However, Applicants intention appears to embrace both substituted and unsubstituted moieties. One skilled in the art cannot envision, for example, a substituted heteroaryl when given that a certain group is a heteroaryl. Appropriate clarification is required, within the claims, indicating that these groups may be substituted along with the list of permitted substituents. Are the other groups, such as, alkyl also optionally substituted when not explicitly stated in the claims?

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

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Applicants are again urgently requested to point to the excluded compounds in the prior art because the disclosure of these compounds is material to the examination of this application. Applicants are requested to point to each excluded compound in a given reference. It is unclear why Applicants have not responded to this query from the previous office action. Are these compounds not excluded to avoid prior art?

Claim Rejections - 35 USC § 103

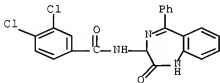
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freidinger et al. (EP 167919). The reference teaches a generic group of benzodiazepines and the compounds in Table 4, page 60. This compound is copied below for Applicants convenience.

RN 103373-21-3 CAPLUS

CN Benzamide, 3,4-dichloro-N-(2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)- (9CI) (CA INDEX NAME)



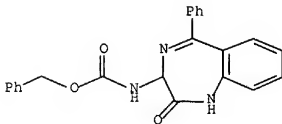
The claims differ by excluding this compound by stating that when R^{6f} is aryl it is not 3,4-dichlorophenyl. However, the claims embrace, for example, 3-bromo-4-chlorophenyl or 2,3-dichlorophenyl.

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One halogen renders another obvious and position isomers are well established as being prima facie structurally obvious. See: Ex parte Engelhardt, 208 USPQ 343, 349; In re Mehta, 146 USPQ 284; In re Surrey, 138 USPQ 67; Ex parte Ulliyot 103 USPQ 185; Ex parte Naito 168 USPQ 437, 439; In re Norris 84 USPQ 459; Ex parte Allais 152 USPQ 66; Ex parte Henkel 130 USPQ 474; Ex parte Biel 124 USPQ 109; In re Crownse 150 USPQ 554; In re Fouche 169 USPQ 431; Ex parte Ruddy 121 USPQ 427; In re Wiechert 152 USPQ 249.

For example “Position Isomerism has been used as a tool to obtain new and useful drugs” (Engelhardt), and “Position isomerism is a fact of close structural similarity” (Mehta, emphasis in the original).

Claims 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bock et al. (US 4,628,084). The reference teaches the compound depicted below.



This compound is excluded by the proviso excluding the $R^{6'}$ from being unsubstituted phenyl $(CH_2)_0-O-$ when $R^{6'}$ is aryl- $(C_1-C_6 \text{ alkyl})-O-$. However, the groups unsubstituted phenyl $(CH_2)_2-O-$ or unsubstituted phenyl $(CH_2)_3-O-$ are included in the claims.

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It has been long established that structural relationship varying the size of a linking carbon chain - is per se obvious. Specifically, In re Shetty, 195 USPQ 753, In re Wilder, 195 USPQ 426 and Ex Parte Gresham 121 USPQ 422 all feature a compound with a C₂ link rejected over a compound with a C₁ link. Similarly, In re Chupp, 2 USPQ 2nd 1437 and In re Coes, 81 USPQ 369 have a C₁ link unpatentable over a C₂ link. Ex parte Ruddy 121 USPQ 427 has a C₃ link unpatentable over a C₁ link. Ex parte Nathan, 121 USPQ 349 found the insertion of a C₂H₄ link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

Copious amount was found during the search that render the claims obvious based on the excluded compounds. Thus, ring position isomers, homologues and differences in the length of alkylene linking claims of the excluded compounds render the instant claims obvious. The prior art considerations have not been continued to include all of the pending claims at this time due to the undue burden placed on the office.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruck Kifle/
Primary Examiner
Art Unit 1624

BK
April 28, 2008